The Claims

1. (currently amended) A drug formulation comprising a drug in an amount effective to provide relief from benign diseases or disorders of the breast in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue, comprising a penetration enhancer to promote delivery of the drug across the stratum corneum, wherein the drug is not a non-steroidal anti-inflammatory or analgesic.

2. (original) The drug formulation of claim 1 wherein the drug is soluble in aqueous solutions.

3. (original) The drug formulation of claim 1 wherein the drug is in the form of micro- or nano-particulates.

4. (original) The drug formulation of claim 1 wherein the carrier is selected from the group consisting of a gel, ointment, lotion, emulsion, cream, foam, mousse, liquid, spray, and aerosol.

5. (original) The drug formulation of claim 4, wherein the carrier is a hydroalcoholic gel.

6. (original) The drug formulation of claim 1 wherein the drug is selected from the group consisting of chemotherapeutic agents, hormones, hormone releasing agents, hormone analogs, and anti-proliferative agents.

7. (original) The drug formulation of claim 6 wherein the drug is selected from the group consisting of danazol, bromocriptine, tamoxifen, luteinizing hormone-releasing hormone (LHRH) analogues, and antiestrogens.

8. (original) The drug formulation of claim 6 wherein the drug is a danazol.

9. (cancelled)

10. (withdrawn, currently amended) A method for treating a disease or disorder of the breast comprising

topically administering to the breast of a patient, a drug formulation suitable for local or regional delivery comprising an effective amount of drug to provide relief from benign diseases and disorders of the breast, in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue, comprising a penetration enhancer to promote delivery of the drug across the stratum corneum, wherein the drug is not a non-steroidal anti-inflammatory or analgesic, in a dosage which results in low serum drug levels as compared to the systemic administration of the drug.

11. (withdrawn) The method of claim 10 wherein the drug is in the form of micro- or nano-particulates.

12. (withdrawn) The method of claim 10 wherein the carrier is selected from the group consisting of a gel, ointment, lotion, emulsion, cream, foam, mousse, liquid, spray, and aerosol.

13. (withdrawn) The method of claim 10 wherein the drug is selected from the group consisting of chemotherapeutic agents, hormones, hormone releasing agents, hormone analogs, and anti-proliferative agents.

14. (withdrawn, currently amended) The method of claim 13 wherein the drug is selected from the group consisting of danazol, bromocriptine, tamoxifen, ~~l-uteinizing~~ luteinizing hormone-releasing hormone (LHRH) analogues, and antiestrogens.

15. (withdrawn) The method of claim 13 wherein the drug is danazol.

16. (cancelled)

17. (withdrawn) The method of claim 16 wherein the benign disease of the breast is selected from the group consisting of mastalgia, mastodynia, Mondor's disease, fibrocystic breast disease, costochondritis, mastitis, Paget's disease of the areola, fibroadenoma, breast abscess, and breast infections.

18. (withdrawn) The method of claim 10 wherein the drug formulation provides a dosage effective for regional treatment.

19. (withdrawn) The method of claim 18 wherein the region is the breast, areola, and underlying musculature of the chest.